EXHIBIT 6

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	)	MDL NO. 1456
	)	CIVIL ACTION: 01-CV-12257-PBS
	)	Judge Patti B. Saris
THIS DOCUMENT RELATES TO *U.S. ex rel. Ven-A-Care of the Florida Keys, Inc. v. Abbott Laboratories, Inc.*, No. 06-CV-11337-PBS	)	Magistrate Judge Marianne B. Bowler

ABBOTT LABORATORIES, INC.'S REVISED FIRST SET OF REQUESTS FOR ADMISSION TO PLAINTIFF UNITED STATES OF AMERICA AND RELATOR VEN-A-CARE OF THE FLORIDA KEYS, INC.

Defendant Abbott Laboratories, Inc. ("Abbott"), pursuant to Rule 36 of the Federal Rules of Civil Procedure, submits the following requests for admission to Plaintiff the United States of America and Relator Ven-A-Care of the Florida Keys, Inc. to be answered under oath within 30 days after service.

The Definitions and Instructions contained in Defendant Abbott Laboratories, Inc.'s First Set of Requests for the Production of Documents and Tangible Things to Plaintiff United States of America and Defendant Abbott Laboratories Inc.'s First Set of Requests for the Production of Documents and Tangible Things to Relator Ven-A-Care of the Florida Keys, Inc. are hereby incorporated by reference.

REQUESTS FOR ADMISSION

Requests For Admission Seeking Authentication Of Documents

1. On August 6, 1968, Irwin Wolkstein, Assistant Director of the Division of Policy and Standards at the U.S. Department of Health, Education and Welfare, wrote a memorandum stating that the "Red book" is a "listing of prices of manufacturers which is often violated by volume and other discounts" and "would be subject to abuse by manufacturers setting prices high to advantage retailers." Exhibit 1 is a true and accurate copy of that memorandum. It was made at or near the time by, or from information transmitted by, a person with knowledge of the

contents of the memorandum, and was made and kept in the course of regularly conducted business activity.

2. In December 1968, a Task Force of the U.S. Department of Health, Education and Welfare published a background paper on payment for prescription drugs, which stated, among other things: "The Red Book and Blue Book do not reflect the actual manufacturers' prices to wholesalers and retailers, which are determined by the amounts of various kinds of discounts." Exhibit 2 is a true and accurate copy of that background paper. It was created at or near the time by, or from information transmitted by, a person with knowledge of its contents, and was made and kept in the course of regularly conducted business activity.

3. Exhibit 3 is a true and correct copy of a brief filed on or about January 12, 1990 by the Department of Health and Human Services in the United States Court of Appeals for the Fifth Circuit in *The State of Louisiana v. The United States Department of Health and Human Services*, Case No. 89-4566 (5th Cir., July 13, 1990). It was made at or near the time by, or from information transmitted by, a person with knowledge of the contents of the record, and was made and kept in the course of regularly conducted business activity.

4. In November 1974, HCFA issued a draft regulation calling for states to pay the lesser of a federally-set MAC or EAC plus a dispensing fee to Providers dispensing Medicaid-covered drugs. 39 Fed. Reg. 41,480 (Nov. 27, 1974). In that draft regulation, HCFA expressly rejected AWP as the benchmark for reimbursement because AWPs "are frequently in excess of actual acquisition cost to the retail pharmacist." Exhibit 4 is a true and accurate copy of that regulation. It was created at or near the time by, or from information transmitted by, a person with knowledge of its contents, and was made and kept in the course of regularly conducted business activity.

5. Commenting on the final regulation setting Medicaid reimbursement in July 1975, HCFA stated that "published wholesale prices often are not closely related to the drug prices actually charged to, and paid by, providers." 40 Fed. Reg. 32,293 (July 31, 1975). Exhibit 5 is a true and accurate copy of that statement. It was created at or near the time by, or from information transmitted by, a person with knowledge of its contents, and was made and kept in the course of regularly conducted business activity.

6. In December 1977, HCFA issued a memorandum to state Medicaid agencies that stated: "The Department is not convinced that those states which continue to reimburse at [AWP] . . . have made a real effort to approach [actual acquisition cost]." HCFA Action Transmittal 77-113 (MMB) (Dec. 13, 1977). Exhibit 6 is a true and accurate copy of that memorandum. It was created at or near the time by, or from information transmitted by, a person with knowledge of its contents, and was made and kept in the course of regularly conducted business activity.

7. Exhibit 7 is a true and accurate copy of Department of Health and Human Services, Departmental Appeals Board, Decision No. 1273 (Aug. 22, 1991), which states: "An audit conducted in 1983 by the HHS Office of the Inspector General (OIG) in six states

(including Arkansas) found that pharmacists' drug costs averaged about 16% below the AWP, and that in only 14 of 3,469 purchases examined did providers pay the AWP or higher (and then for extenuating reasons)." This decision was created at or near the time by, or from information transmitted by, a person with knowledge of its contents, and was made and kept in the course of regularly conducted business activity.

8. In June 1984, HHS-OIG published a report of its audit of pharmacy drug purchases in six states, titled "Changes to the Medicaid Prescription Program Could Save Millions" (the "June 1984 HHS-OIG Audit Report"), which found that 99.6 percent of the 3,469 pharmacy purchases audited were made at prices averaging approximately 15.93 percent below AWP, as a result of purchase and trade discounts that were routinely available to purchasing pharmacies. Exhibit 8 is a true and accurate copy of that report. It was created at or near the time by, or from information transmitted by, a person with knowledge of its contents, and was made and kept in the course of regularly conducted business activity.

9. HCFA informed all state Medicaid agencies in a Medicaid Action Transmittal dated September 1984 (No. 84-12) that "[w]ithin the pharmaceutical industry, AWP means undiscounted list price. Pharmacies purchase drugs at prices that are discounted significantly below AWP or list price. . . . Excessive payments are being made nationwide for the ingredient cost of prescription drugs under the Medicaid program. The purpose of this report is to alert Department management to the opportunity for significant reductions in program expenditures if actions are taken to stop the present widespread use of [AWP] in determining program reimbursement for prescription drugs." Exhibit 9 is a true and accurate copy of that transmittal letter. It was created at or near the time by, or from information transmitted by, a person with knowledge of its contents, and was made and kept in the course of regularly conducted business activity.

10. In a 1986 survey report on Hawaii's Medicaid Program, HCFA Region IX stated that HHS (then known as HEW) "believed that published [AWPs], which were being used as a major pricing reference for reimbursement of prescription drugs in the Medicaid program, were not representative of the prices pharmacists paid for drugs." HHS also stated in this report that "[i]t is apparent from this review that AWP, which is the basis for the State's EAC, is not a reliable predictor of the prices pharmacists actually pay for drugs." The report further stated that the survey showed that "pharmacies generally purchase drugs at prices that are discounted significantly below AWP" and that "AWPs are not determined by surveying market transactions and thus do not accurately reflect prices pharmacists pay for drug products." Exhibit 10 is a true and accurate copy of that survey report. It was created at or near the time by, or from information transmitted by, a person with knowledge of its contents, and was made and kept in the course of regularly conducted business activity.

11. In a speech given on Sept. 28, 1987 at the Symposium on the New Medicaid Regulations on Drug Reimbursement, Robert Helms, Ph.D., Assistant Secretary for Planning and Evaluation at HHS, stated, among other things, that a 1982 Task Force appointed by Secretary Schweiker identified the "clear unworkability of the MAC process," "arbitrary and unfair results," and the "artificiality" of "Red Book prices." Exhibit 11 (HHC902-1078 through

HHC902-1089) is a true and accurate copy of Mr. Helms' remarks. It was made at or near the time by, or from information transmitted by, a person with knowledge of the contents of the remarks, and was made and kept in the course of regularly conducted business activity.

12. On April 26, 1988, HCFA's Region VI chief state operations officer, Don Hearn, in a letter to the Office the Director, Bureau of Eligibility, Reimbursement and Coverage, stated: "It has been repeatedly shown that AWP is an inflated figure and does not comply with [statutory requirements] that Medicaid payments be consistent with efficiency, economy, and quality of care. We also believe that use of the AWP cannot meet the definition of EAC found at CFR 447.301, i.e. the 'agency's best estimate of the price generally and currently paid by providers for a drug marketed or sold by a particular manufacturer or labeler in the package size most frequently purchased by providers.'" Exhibit 12 (HHC011-0861 through HHC001-0862) is a true and accurate copy of that letter. It was made at or near the time by, or from information transmitted by, a person with knowledge of the contents of the letter, and was made and kept in the course of regularly conducted business activity.

13. On or about May 16, 1988, the HCFA Administrator stated in a letter disapproving Louisiana's State Plan Amendment No. 87-33: "We believe there is a preponderance of evidence that demonstrates that AWP significantly overstates the price that pharmacy providers actually pay for drug products and, thus, is not 'the price generally and currently paid by providers.' The continued use of AWP results in significant potential overpayments to pharmacy providers." Exhibit 13 is a true and accurate copy of that letter. It was created at or near the time by, or from information transmitted by, a person with knowledge of its contents, and was made and kept in the course of regularly conducted business activity.

14. On August 12, 1988, HCFA's Regional Administrator, J.D. Sconce, informed U.S. Senator Dale Bumpers in a letter that "[t]here is a preponderance of evidence that demonstrates that the published AWP significantly overstates the price that pharmacy providers actually pay for drug products and, thus, is not 'the price generally and currently paid by providers." Exhibit 14 (HCC011-2189 through HHC001-2190) is a true and accurate copy of that letter. It was made at or near the time by, or from information transmitted by, a person with knowledge of the contents of the letter, and was made and kept in the course of regularly conducted business activity.

15. On September 22, 1988, HCFA's Program Analysis Officer, Peter Rodler, testified under oath as follows: "In early November 1983, the Secretary of [HHS] appointed a, I believe, four member task force to conduct public hearings to obtain comments from concerned individuals as to ways in which the current Medicaid drug regulations could improve. It was a three day session in which I was present and the executive's secretary of the National Wholesale Druggist Association, which is the professional association of wholesalers that sell drugs nationwide, testified that AWP is like the sticker price on an automobile. It is the very highest price that anyone would be expected to pay for the drug product. I remember that statement very clearly. Obviously I spent twelve years in reimbursement policy for the Medicaid program, and that statement has significant meaning." Exhibit 15 contains a true and accurate copy of that testimony. It was created at or near the time by, or from information transmitted by, a person

with knowledge of its contents, and was made and kept in the course of regularly conducted business activity.

16. Also on September 22, 1988, HCFA's Region VI Medical Policy Specialist, Nancy Saltzman, testified under oath as follows: "I don't think anyone has ever disputed the fact – or to my knowledge that I've spoken with, has ever disputed the fact that discounts are there. I think there is – some people believe that those discounts are not available under certain circumstances, such as you have to buy "X" number of dollars to receive those or you have to pay your bills on time or what have you. There are various types of discounts, and we found that before and we found that again. The OIG found the same thing. But they're always there and I will not say always available, but if a provider meets the criteria – let me put it this way, there are things, discounts that we call routine discounts, and to us, that means those discounts are always available to the pharmacists. They're trade discounts, as Mr. Rodler testified earlier. The wholesalers do not consider AWP to be the price that is paid by pharmacists routinely to purchase drug products. There are instances, we have been told, where a provider may actually pay AWP. I have had one or two providers tell me they'll pay AWP if they have to go down the street and buy it from another provider, that product from another provider. If they need it today or overnight and they can't get it from their primary wholesaler or manufacturer, whoever they buy it from, they may get it from a secondary source that they don't do business with all the time or very much dollar business with, and they may be charged and pay the AWP. But again, I would say, guessing, probably ninety to ninety-five percent of the purchases are made at prices below the AWP, and that's confirmed by what the wholesalers tell us. Interviews with wholesalers, interview with pharmacists, in prior years, in current years." Exhibit 16 contains a true and accurate copy of that testimony. It was created at or near the time by, or from information transmitted by, a person with knowledge of its contents, and was made and kept in the course of regularly conducted business activity.

17. In July 1989, HCFA's Associate Regional Director for Region IX , Lawrence L. McDonough, stated as follows in a letter to the Deputy Director of California's Department of Health Services, John Rodriguez: "While we can understand that the term 'average wholesale price' connotes what pharmacies pay for drug products, in the pharmaceutical industry it is commonly understood to be higher than actual costs. There have been a number of studies which indicate that the published AWP overstates actual prices paid by as much as 10-25 percent because of discounts, premiums, special offers or incentives." Exhibit 17 (HHC016-0747 through HHC016-0748) is a true and accurate copy of that letter. It was made at or near the time by, or from information transmitted by, a person with knowledge of the contents of the letter, and was made and kept in the course of regularly conducted business activity.

18. HCFA's Acting Administrator, Louis B. Hays, testified before the Senate Special Committee on Aging in 1989 that "[w]hile the term 'average wholesale price' is suggestive of the amount that pharmacies actually pay for the drugs, it is in fact significantly higher than actual costs. The average wholesale price is somewhat comparable to the manufacturer's sticker price on a new car." Mr. Hays' prepared written statement adds: "this is rarely the price actually paid for the car." Exhibit 18 is a true and accurate copy of this testimony. It was created at or near the time by, or from information transmitted by, a person with knowledge of its contents, and was made and kept in the course of regularly conducted business activity.

19. In 1989, the Senate Special Committee on Aging issued a report stating that AWP exceeds actual drug prices, that the Department of Veteran's Affairs received an average discount of 41% off of AWP for single source drugs and an average of 67% off of AWP for multiple source sources, and that hospitals, HMOs, and nursing homes that contract with wholesalers achieve discounts up to 99% off AWP. Majority Staff Report, Special Committee of Aging, United States Senate, *"Prescription Drug Prices: Are We Getting Our Money's Worth?,"* S. Rep. 101-49 at 11 (1989). Exhibit 19 is a true and accurate copy of that report. It was created at or near the time by, or from information transmitted by, a person with knowledge of its contents, and was made and kept in the course of regularly conducted business activity.

20. On or around July 31, 1989, Senator David Pryor (D-Ark) made statements in the U.S. Senate about Medicare reimbursement for drugs. Among other things, Senator Pryor commented: "After all the charts and all the graphs and all the words, it comes down to this: for the same bottle of prescription drugs, different buyers pay dramatically different prices. For example, if we look at the price of the brand-name painkiller 'Motrin,' the published list price is $32. If the new Medicare prescription drug benefit were currently in place, Medicare would pay $29. Mr. President, the Veterans' Administration has been smart. They have gone and dealt with drug manufacturers. They say, 'We want a better price.' The bottom line is that the Veterans' Administration pays a price of $5 for a bottle of capsules of Motrin. Medicare pays $29 for the same bottle." 135 Cong. Rec. 9059 (daily ed. July 31, 1989) (statement of Sen. Pryor). Exhibit 20 is a true and accurate copy of that testimony. It was created at or near the time by, or from information transmitted by, a person with knowledge of its contents, and was made and kept in the course of regularly conducted business activity.

21. In October 1989, the HHS-OIG issued a report on Medicaid reimbursement that stated: "[W]e continue to believe that AWP is not a reliable price to be used as a basis for making reimbursements for either the Medicaid or Medicare Programs." *Use of Average Wholesale Price in Reimbursing Pharmacies Participating in Medicaid and the Medicare Prescription Drug Program* (A-06-89-00037) (Oct. 1989). Exhibit 21 is a true and accurate copy of that report. It was created at or near the time by, or from information transmitted by, a person with knowledge of its contents, and was made and kept in the course of regularly conducted business activity.

22. Relying on the October 1989 HHS-OIG Report, HCFA revised its State Medicaid Manual to instruct State Medicaid agencies not to use AWP as a drug's EAC for Medicaid reimbursement purposes "without a significant discount being applied." HCFA, State Medicaid Manual § 6305.1. Exhibit 22 is a true and accurate copy of that provision of the HCFA State Medicaid Manual. It was created at or near the time by, or from information transmitted by, a person with knowledge of its contents, and was made and kept in the course of regularly conducted business activity.

23. On October 5, 1989, HCFA informed the Arkansas Department of Health Services in a letter: "The published AWP is not an acceptable measure because it is frequently inflated and does not reflect the various incentives, sales promotions, discounts and allowances (other than discounts for cash or prompt payment) that are routine terms of purchasing in the

drug marketplace." Exhibit 23 (HHC010-0969 through HHC010-0970) is a true and accurate copy of that letter. It was made at or near the time by, or from information transmitted by, a person with knowledge of the contents of the letter, and was made and kept in the course of regularly conducted business activity.

24. In 1990, Secretary of HHS Louis Sullivan testified before Congress: "Many studies and most information available on this subject show that the list prices for drug products—commonly known as Average Wholesale Price (AWP)—rarely, if ever, reflect the prices pharmacies actually pay . . . . Since 1976, our policy has been that AWP is not an acceptable measure of EAC." *Medicaid Prescription Drug Pricing: Hearing on S. 2605 and S. 3029 Before the Senate Committee on Finance, 101st Cong. 308-310 (1990).* Exhibit 24 is a true and accurate copy of that testimony. It was created at or near the time by, or from information transmitted by, a person with knowledge of its contents, and was made and kept in the course of regularly conducted business activity.

25. On May 8, 1990, Senator Pryor made the following statement in the United States Senate: "There are two domestic markets in the U.S. for most big-selling prescription drugs: a price-competitive market, characterized by deep discounts off the published list price (benefiting the Department of Veterans Affairs, hospitals, and managed care plans, such as HMOs), and a high-priced market where retail customers, Medicare, and Medicaid purchase their prescription drugs ." He further commented that the Department of Veterans Affairs "achieves an average discount of 41% off the manufacturer's published 'Average Wholesale Price' (AWP) for single source drugs and an average of over 60% off the AWP for multiple source drugs. In contrast, Medicaid programs, in almost all cases, pay top dollar (or at best, AWP minus 10%) for drug products." 136 Cong. Rec. E5814 (daily ed. May 8, 1990) (statement of Sen. Pryor). Exhibit 25 is a true and accurate copy of that statement. It was created at or near the time by, or from information transmitted by, a person with knowledge of its contents, and was made and kept in the course of regularly conducted business activity.

26. On May 10, 1990, Senator David Pryor (D-Ark) made the following statement in the U.S. Senate: "I have brought with me today two medicine bottles that illustrate the shameful situation we must correct. I would ask my colleagues to note that these two bottles are the same. They're the same because they contain the same quantity of the same drug to treat serious stomach ulcers--a drug called Zantac--and because they were both made by the same brand name manufacturer. But one of these bottles was purchased by the Veteran's Administration for $34, while the other was purchased by the Medicaid program for $68. An antiasthma medication made by Schering-Plough that is sold to the Veterans' Administration for $8 while an identical package of the drug commands three times as much--$24--from the fiscally struggling Medicaid Program. And I could just as easily have brought in bottles of the very popular antihypertensive drug called Dyazide. For 2 years now, the Veteran's Administration has negotiated a price of $50 for a 1,000 capsules, but Medicaid pays about $280 for the same package from the same company. Mr. President, as talented as the negotiators at the Veterans' Affairs are, they aren't the only people getting access to good prices for prescription drugs. Besides the vast majority of hospitals and HMO's in this country, other industrialized nations of the world are getting much better deals as well." 136 Cong. Rec. S5986 (daily ed. May 10, 1990) (statement of Sen. Pryor). Exhibit 26 is a true and accurate copy of that statement. It was created at or near the time by, or

from information transmitted by, a person with knowledge of its contents, and was made and kept in the course of regularly conducted business activity.

27. In July 1990, HCFA's M. J. Christenberry, Associate Regional (Region VI) Administrator, Division of Medicare, sent a memo to HCFA's Kathleen Buto, Director, Bureau of Policy Development that stated: "We believe it is time to revise Medicare's drug payment policy for several reasons." One of the reasons cited was that "[p]rices in the Red Book are inflated and do not represent physicians' and suppliers' acquisition costs" and that Red Book prices "are 'well above the prices at which supplier can purchase these factors' and 'substantial discounts are available'." Exhibit 27 (HHC906-0093 through HHC906-0098) is a true and accurate copy of that memo. It was made at or near the time by, or from information transmitted by, a person with knowledge of the contents of the letter, and was made and kept in the course of regularly conducted business activity.

28. On or around September 12, 1990, Congressmen Ron Wyden (D-Or.) and Jim Cooper (D-Tenn.) introduced a bill in U.S. House of Representatives titled the "Medicaid Prescription Drug Fair Access and Pricing Act of 1990." In extension of remarks made in the Congressional Record, Representative Wyden stated: "Medicaid isn't getting competitive prices because Medicaid has never required competitive prices." He also stated that the VA paid an average of 41 percent less for drugs than the Medicaid Program, and displayed charts comparing VA prices and Medicaid reimbursement. For single source drugs, the charts showed an example where Medicaid paid 93% more than the Federal Government. For multi-source drugs, the chart showed percentage differences of 1130% and 5000%. 136 Cong. Rec. E2813 (daily ed. Sept. 12, 1990) (statement of Rep. Wyden). Exhibit 28 is a true and accurate copy of that statement. It was created at or near the time by, or from information transmitted by, a person with knowledge of its contents, and was made and kept in the course of regularly conducted business activity.

29. HHS' Appeals Board stated as follows in a decision on August 22, 1991: "In the mid-1970's, HCFA had proposed to limit payment to actual acquisition costs, apparently to counter the practice of using the AWP in national drug pricing publications. Determining actual costs was burdensome, however, and the agency ultimately decided to specify use of estimate costs in its regulations." Department of Health and Human Services, Departmental Appeals Board, Decision No. 1273 (Aug. 22, 1991). Exhibit 29 is a true and accurate copy of that decision. It was created at or near the time by, or from information transmitted by, a person with knowledge of its contents, and was made and kept in the course of regularly conducted business activity.

30. On August 12, 1992, HCFA's Associate Regional Administrator for Region X, Albert J. Benz, wrote a memo stating: "[B]ecause of variations in carrier calculation methodologies, there is the potential for carriers to derive different AWP amounts from the same data. The carriers in this region have informed us that these calculations are tremendously time consuming. One carrier estimated that over a month of staff time was required to perform this task. The present practice of each carrier calculating the AWP independently is duplicative, prone to errors and variances in payment amounts and extremely expensive. If the costs to all the carriers are considered, they would run into the tens of thousands of dollars" (emphasis in

original). Exhibit 30 (HHC903-0976 through HHC903-0977) is a true and accurate copy of that memorandum. It was made at or near the time by, or from information transmitted by, a person with knowledge of the contents of the memorandum, and was made and kept in the course of regularly conducted business activity.

31. An HHS-OIG report dated November 6, 1992, titled *Physicians' Costs for Chemotherapy Drugs* (A-01-91-01049), stated that "[H]igh dollar volume chemotherapy drugs are available at a cost below AWP. For example, one of the five providers submitted a claim for drugs administered on March 7, 1991. Analysis showed that each drug's cost was below AWP and that the total cost for the drugs claimed was 48% of AWP." Exhibit 31 is a true and accurate copy of that report. It was created at or near the time by, or from information transmitted by, a person with knowledge of its contents, and was made and kept in the course of regularly conducted business activity.

32. An HHS-OIG report dated October 20, 1992, titled *Cost of Dialysis-Related Drugs* (A-01-91-00526), included a chart on p.6 showing that based on surveys of actual invoice prices at 30 dialysis facilities during May 1991, the EAC of Vancocin/Vancomycin 500 ML was $5.00 and the median AWP for the same drug was $19.17. Exhibit 32 is a true and accurate copy of that report. It was created at or near the time by, or from information transmitted by, a person with knowledge of its contents, and was made and kept in the course of regularly conducted business activity.

33. A 1993 GAO report, which studied drug acquisition cost and Medicaid reimbursement in Maryland and Illinois, found that Medicaid reimbursement exceeded drug acquisition cost by 10-23% in Illinois, and by 11-34% in Maryland. *Medicaid: Outpatient Drug Costs and Reimbursements for Selected Pharmacies in Illinois and Maryland*, GAO Report (HRD-93-55FS) (Mar. 18, 1993). Exhibit 33 is a true and accurate copy of that report. It was created at or near the time by, or from information transmitted by, a person with knowledge of its contents, and was made and kept in the course of regularly conducted business activity.

34. In a memorandum dated November 2, 1993, the Director of the Medicare Carrier Operations Branch for Region X, Fred Rosen, stated to Carol Walton, Director, Bureau of Program Operations: "We believe that the area of drug pricing continues to be an area where there are huge carrier fee discrepancies for the same products. Medicare carriers have great latitude in establishing drug pricing since Medicare regulations are broad and HCPC coding does not fully reflect various drug concentrations, dosages and packages." He also stated that the "continued use of Drug Topics Redbook or Medispan, as the source for AWP data is still a problem, since AWP data reported in these publications, by all accounts, is greatly inflated." Exhibit 34 (HHC019-0291 through HHC019-0292) is a true and accurate copy of that memorandum. It was made at or near the time by, or from information transmitted by, a person with knowledge of the contents of the memorandum, and was made and kept in the course of regularly conducted business activity.

35. A letter addressed to all Region IV Medicare Carriers and dated May 25, 1994 stated: "In accordance with 42 CFR 405.517, carriers may, but are not required to, take into

account overhead costs such as inventory and spoilage, in determining the EAC. This could be determined based on actual cost surveys or other means. For example, a carrier might determine that an overhead allowance of 10 percent above the material costs would be equitable in establishing the EAC." Exhibit 35 (AWP057-0832 through AWP057-0833) is a true and accurate copy of that letter. It was made at or near the time by, or from information transmitted by, a person with knowledge of the contents of the memorandum, and was made and kept in the course of regularly conducted business activity.

36. On October 17, 1994, the Chief of the Medicare Technical Issues Section, Frank J. Camozzi, wrote a letter to Susan Coonfield, Manager of Medicare Claim Administration at Aetna Life Insurance Company, that stated: "In July [1994], because of a protest under the Reduction of Paperwork Act, the Office of Management and Budget asked that we suspend the surveys being conducted to arrive at an estimated acquisition cost. Thus, at this time, all carrier drug pricing is based on the AWP." Exhibit 36 (HHC015-1677 through HHC015-1679) is a true and accurate copy of that letter. It was made at or near the time by, or from information transmitted by, a person with knowledge of the contents of the letter, and was made and kept in the course of regularly conducted business activity.

37. On February 2, 1995, the Chief of the Medicare Technical Issues Section, Frank J. Camozzi, wrote a letter to Celeste Brose, Supervisor, Focused Medical Review, Blue Shield of California, that stated: "Drugs are [paid] at the lowest of the national Average Wholesale Price (AWP), Estimated Acquisition Cost (EAC) or actual charge. As no method for arriving at the EAC has been approved, drugs are priced at AWP." Exhibit 37 (HHC015-1618) is a true and accurate copy of that letter. It was made at or near the time by, or from information transmitted by, a person with knowledge of the contents of the letter, and was made and kept in the course of regularly conducted business activity.

38. A February 26, 1996 Barron's Magazine article stated: "Much of the revenues of an oncology practice, and often most of the profits come from hefty markups of the prices of cancer drugs. These drug mark ups which can be 60% or more, are a ready target for HMOs and the federal government's increasingly strapped Health Care financing agency." The article also stated: "The big bills for cancer treatment start with the manufacturers who can set high wholesale prices for chemo drugs because there is little competition," "but oncologists tack on their own profit margin when they bill for drugs. Anecdotes abound about the size of mark ups and their importance to the profits at oncology practices." *Painful Profits: Cancer Treatment Firms May Soon See Plump Margins Slashed,* Barron's Magazine (Feb. 26, 1996). Exhibit 38 is a true and accurate copy of that article. It was created at or near the time by, or from information transmitted by, a person with knowledge of its contents, and was made and kept in the course of regularly conducted business activity.

39. A June 10, 1996 Barron's Magazine article stated: "For many drugs, especially the growing number coming off patent and going generic, the drug providers actually pay wholesale prices that are 60-90% below the so-called average wholesale price, or AWP, used in reimbursement claims." *Hooked on Drugs: Why Do Manufacturers Pay Such Outrageous Prices For Pharmaceuticals?,* Barron's Magazine (June 10, 1996). Exhibit 39 is a true and

accurate copy of that article. It was created at or near the time by, or from information transmitted by, a person with knowledge of its contents, and was made and kept in the course of regularly conducted business activity.

40. On August 5, 1996, Dr. Grant E. Steffen of CMS wrote a letter to Jill Merrill, Medicare Program, HCFA (Denver, Colorado), that stated: "Is it not possible for HCFA and the OMB to collaborate on a set of questions that would constitute a valid survey of acquisition costs? Today I received Ms. Debus' letter stating that a RIL dated August 12, 1996 [sic] requested that this carrier suspend any effort to survey physicians for AC. Until today, I was not aware of this RIL. Two years have passed and there has been no visible attempt at collaborating on a valid survey. Perhaps such a collaboration is more difficult than I can imagine, or perhaps this is a low-priority issue for HCFA." Exhibit 40 (HHC014-0172 through HHC014-0176) is a true and accurate copy of that letter. It was made at or near the time by, or from information transmitted by, a person with knowledge of the contents of the letter, and was made and kept in the course of regularly conducted business activity.

41. In 1997, HCFA's Grace Witles, Health Insurance Specialist, Bureau of Policy Development, wrote a letter to Senator Joe Lieberman that stated: "The Office of the Inspector General has issued several reports indicating that, on average, Medicare pays approximately 15 percent above the cost of drugs. In some individual cases this mark-up is much higher. We believe that the program is intended to pay physicians for their professional services and expertise, and not to pay a profit on the drugs they furnish. While in the past the program's payment for drugs may have included the cost of wastage and storage, etc., that will no longer be true." Exhibit 41 (HHC003-0507 through HHC003-0508) is a true and accurate copy of that letter. It was made at or near the time by, or from information transmitted by, a person with knowledge of the contents of the letter, and was made and kept in the course of regularly conducted business activity.

42. On Jan. 21, 1997 HHS-OIG issued a report, titled *Review of Pharmacy Acquisition Costs for Drugs Reimbursed Under the Medicaid Prescription Drug Program of the Missouri Department of Social Services*, which stated: "[W]e determined that there is a significant difference between AWP and pharmacy acquisition costs." Referring to a June 10, 1996 Barron's Magazine article, the report stated: "Barron's compared about 300 dose forms of the top 20 Medicare drugs and concluded that the true cost was 10 to 20 percent below AWP for brand name drugs and 60 to 85 percent below AWP for generic drugs. Barron's also reported that industry insiders joke that AWP really means 'Ain't What's Paid.'" Exhibit 42 is a true and accurate copy of this report. It was created at or near the time by, or from information transmitted by, a person with knowledge of its contents, and was made and kept in the course of regularly conducted business activity.

43. On May 29, 1997, HCFA's Adrienne M. Kaylor, Health Insurance Specialist, Bureau of Policy Development, informed Senator Russell Feingold that a proposal in the 1998 budget bill would require that Medicare "pay for drugs based on the physician's or supplier's acquisition cost for the drug. In this way, the program would pay the price charged to the physician or supplier and eliminating any markup." Exhibit 43 (HHC003-0498 through

HHC003-0502) is a true and accurate copy of that letter. It was made at or near the time by, or from information transmitted by, a person with knowledge of the contents of the letter, and was made and kept in the course of regularly conducted business activity.

44. On June 11, 1997 a member of the Virginia Carrier's Advisory Committee wrote a letter to HCFA that stated: "Instead of being reimbursed by Medicare for the actual cost, the acquisition price, [physicians] receive a far larger sum based on [AWP]. The difference between the two prices, which can be considerable, is kept by the purchaser." Exhibit 44 (HHC003-0514 through HHC003-0515) is a true and accurate copy of that letter. It was made at or near the time by, or from information transmitted by, a person with knowledge of the contents of the letter, and was made and kept in the course of regularly conducted business activity.

45. A June 24, 1997 House Committee Report accompanying the Balanced Budget Act of 1997 stated: "The Inspector General for the Department of Health and Human Services has found evidence that over the past several years Medicare has paid significantly more for drugs and biologicals than physicians and pharmacists pay to acquire such pharmaceuticals. For example, the Office of the Inspector General reports that Medicare reimbursement for the top 10 oncology drugs ranges from 20 percent to nearly 1000 percent per dosage more than acquisition costs." H.R.Rep. No.105-149, at 1354. Exhibit 45 is a true and accurate copy of that report. It was created at or near the time by, or from information transmitted by, a person with knowledge of its contents, and was made and kept in the course of regularly conducted business activity.

46. In the legislative history to the 1997 BBA, a House Report stated that HHS-OIG reports had found that "Medicare reimbursement for the top 10 oncology drugs ranges from 20 percent to nearly 1000 percent per dosage more than acquisition costs." H. Rep. No. 105-149 at 1354 (1997). Exhibit 46 is a true and accurate copy of that report. It was created at or near the time by, or from information transmitted by, a person with knowledge of its contents, and was made and kept in the course of regularly conducted business activity.

47. In a written response to a question posed by Senator Orrin Hatch during deliberations on the 1997 BBA, Secretary Donna Shalala stated: "Medicare pays the [AWP] for covered drugs. However, the AWP is not the average price actually charged by wholesalers to their customers. Rather, it is a 'sticker' price set by drug manufacturers and published in several commercial catalogs." *Hearing on President's Fiscal Year 1998 Budget Proposal for Medicare, Medicaid, and Welfare Before the Senate Committee on Finance*, 105th Cong. 265 (1997) (written response of Secretary Donna Shalala to questions of Senator Hatch). Exhibit 47 is a true and accurate copy of that statement. It was created at or near the time by, or from information transmitted by, a person with knowledge of its contents, and was made and kept in the course of regularly conducted business activity.

48. An October 1, 1997 internal HHS memorandum from Nancy-Ann Min DePerle, HCFA Deputy Administrator, to June Gibbs Brown, Inspector General, stated that an HHS-OIG report concluded: "The published AWPs currently used by Medicare carriers to determine reimbursement do not resemble the actual wholesale prices which are available to the physician and supplier communities that bill for these drugs." Exhibit 48 (AWP019-1277 through

AWP019-1278) is a true and accurate copy of that memorandum. It was made at or near the time by, or from information transmitted by, a person with knowledge of the contents of the memorandum, and was made and kept in the course of regularly conducted business activity.

49. Congressman Pete Stark wrote HHS on December 8, 1997 and stated: "The Administration should be congratulated for trying to achieve these savings in this year's budget bill. Unfortunately, because of aggressive, shameless lobbying Congress defeated the Administration's actual acquisition cost (AAC) proposal and you were presented with a continuation of the worthless average wholesale price system." Exhibit 49 (HHC001-0365 through HCC001-0366) is a true and accurate copy of Mr. Stark's letter. It was made at or near the time by, or from information transmitted by, a person with knowledge of the contents of the letter, and was made and kept in the course of regularly conducted business activity.

50. Following passage of the 1997 BBA, President Clinton stated in a radio address to the nation: "Sometimes the waste and abuses aren't even illegal; they're just embedded in the practices of the system. These overpayments occur because Medicare reimburses doctors according to the published average wholesale price—the so-called sticker price—for the drugs. Few doctors, however, actually pay the full sticker price." White House Office of Press Secretary, Remarks by the President in Radio Address to the Nation, 1997 WL 767416 (White House Dec. 13, 1997). Exhibit 50 is a true and accurate copy of President Clinton's remarks. It was created at or near the time by, or from information transmitted by, a person with knowledge of its contents, and was made and kept in the course of regularly conducted business activity.

51. A December 1997 HHS-OIG report, titled *Excessive Medicare Payments For Prescription Drugs*, stated: "Although Medicare's reimbursement methodology for prescription drugs does not provide for different payment rates based on geographical factors, the allowed amounts for individual drug codes varied among the carriers." It also stated that, "[f]or some drug codes, the differences in allowed amounts were significant" and that "variations would seem to be caused by carriers' decisions regarding when to update reimbursement, what sources to use for documenting AWPs, and in the case of multiple-source drugs, which generic drugs to include in calculating the median statistic." The report stated further that its findings "provide evidence that Medicare and its beneficiaries are making excessive payments for prescription drugs. The published AWPs that are currently being used by Medicare-contracted carriers to determine reimbursement bear little or no resemblance to actual wholesale prices that are available to the physicians and supplier communities that bill for drugs." Exhibit 51 is a true and accurate copy of that report. It was created at or near the time by, or from information transmitted by, a person with knowledge of its contents, and was made and kept in the course of regularly conducted business activity.

52. On March 3, 1998, in a hearing before the House Subcommittee on Health of the Committee on Ways and Means, Congressman Pete Stark stated: "[D]octors[] [are] opposing the President's proposal for paying for drugs on the basis of acquisition cost rather than on this so-called average wholesale price which is sort of the equivalent of the sticker price on an automobile. If you know anybody who paid that for their car, you found somebody to sell a bridge to. These drugs are reimbursed by Medicare at 10 times the amount the doctor pays for

them." *Reports Regarding Medicare Payment Policies: Hearing Before the Committee on Ways and Means*, 105th Cong. 31 (1998) (statement of Rep. Stark, Member, Subcomm. on Health) at 31. Exhibit 52 is a true and accurate copy of that statement. It was created at or near the time by, or from information transmitted by, a person with knowledge of its contents, and was made and kept in the course of regularly conducted business activity.

53. On October 9, 1998, Rep. Harold Ford, Jr. (D-Tn) inserted into the Congressional Record a report that stated: "The best publicly available indictor [sic] of the prices companies charge their most favored customers, such as large insurance companies and HMOs, is the Federal Supply Schedule (FSS). The FSS is a price catalog containing goods available for purchase by federal agencies. Drug prices on the FSS are negotiated by the [VA]. The prices on the FSS closely approximate the prices that the drug companies charge their most favored nonfederal customers. According to the [GAO], '[u]nder [General Services Administration] procurement regulations, VA contract officers are required to seek an FSS price that *represents the same discount off a drug's list price that the manufacturer offers its most-favored nonfederal customer under comparable terms and conditions*.'" *Prescription Drug Pricing in the 9th Congressional District in Tennessee: Drug Companies Profit At The Expense of Older* Americans, 144 Cong. Rec. E2063 (October 11, 1998) (report submitted by Rep. Ford) (emphasis in original). Also on October 9, 1998, Rep. Ford submitted into the Congressional Record results related to a pricing study performed in his district. The study indicated that differences between retail prices and prices for favored customers for the top 10 drugs for senior citizens ranged from 76% to 258%, with an average differential of 115%. Rep. Ford stated that local pharmacies "appear to have relatively small markups between the prices at which they buy prescription drugs and the prices at which they sell them. The retail prices in Tennessee are 8% above the published national Average Wholesale Price. The differential between retail prices and a second indicator of pharmacy costs, the prices from one wholesaler, is only 27%." 144 Cong. Rec. E2061, E2062 (daily ed. Oct. 9, 1998) (reported submitted by Rep. Ford). Exhibit 53 is a true and accurate copy of these statements. It was created at or near the time by, or from information transmitted by, a person with knowledge of its contents, and was made and kept in the course of regularly conducted business activity.

54. HCFA employee Fay Baier stated in an email in 1998: "If the situation is anything like the cancer drugs, the urologists will purchase the drug for pennies on the dollar and then bill Medicare the full allowed amount; this can be quite lucrative." Exhibit 54 (HHC908-1266) is a true and accurate copy of that email. It was made at or near the time by, or from information transmitted by, a person with knowledge of the contents of the email, and was made and kept in the course of regularly conducted business activity.

55. On April 21, 1999, Congressman Pete Stark (D-Cal) wrote a letter to Nancy-Ann Min DeParle, the Administrator of HCFA. In that letter, Congressman Stark strongly urged HCFA to immediately issue written guidance to State Medicaid Programs and Medicare Carriers to approve the use of new pricing information from First Data Bank relating to certain injection, infusion and inhalation drugs and biologicals. The new pricing information was developed in connection with DOJ, HHS-OIG, HCFA, and NAMFCU. Congressman Stark stated that every day HCFA waited to implement the new pricing information, Medicare and Medicaid wasted more money in reimbursing drugs. Exhibit 55 (HHC001-0733 through HHC001-0734) is a true

and accurate copy of that letter. It was made at or near the time by, or from information transmitted by, a person with knowledge of the contents of the letter, and was made and kept in the course of regularly conducted business activity.

56. Exhibit 56 (HHC902-0801 through HHC902-0818) is a true and accurate copy of a report submitted to Congress by Donna Shalala, the Secretary of HHS on or about July 1, 1999. It was made at or near the time by, or from information transmitted by, a person with knowledge of the contents of the report, and was made and kept in the course of regularly conducted business activity.

57. On June 15, 1999, in an extension of his remarks regarding the proposed Medicare Early Access Act, Rep. Pete Stark stated that the act provided for "Medicare payment for pharmaceuticals, biologicals, or parenteral nutrients on the basis of actual acquisition cost rather than the average wholesale price which is often far above the price at which the drug can really be purchased." 145 Cong. Rec. E1251, E1252 (daily ed. June 15, 1999) (statement of Rep. Stark). Exhibit 57 is a true and accurate copy of that statement. It was created at or near the time by, or from information transmitted by, a person with knowledge of its contents, and was made and kept in the course of regularly conducted business activity.

58. In an email sent on October 5, 1999, CMS Region VI employee Margaret Cano stated: "In my conversation with one of the consultants from Myers and Stauffer, (Allen) he told me that the cost of the drugs given to him did not include the discounts which were received by the pharmacies. He also stated that the 17.3% discount shown for the AWP was only an average, that in reality there were much larger discounts received by some of the pharmacies. The old formula used by Arkansas rendered almost 100% profit." Exhibit 58 (HHC010-0834) is a true and accurate copy of that email. It was made at or near the time by, or from information transmitted by, a person with knowledge of the contents of the email, and was made and kept in the course of regularly conducted business activity.

59. On May 31, 2000, HHS Secretary Donna Shalala sent a letter to Hon. Thomas Bliley, Chairman of the House Commerce Committee stating: "Based on our recent discussions with the Department of Justice and HHS Inspector General, we believe that the Administration's original approach—to base Medicare's payment for drugs on the physician's actual acquisition costs, perhaps adjusted for a reasonable handling fee—is probably the most effective means to ensure that Medicare is paying fairly. As part of this effort, we plan to work with physician groups to review physicians' ability to provide acquisition cost data, and to review payment rates for chemotherapy administration to ensure that they are adequate as we reduce payments for the drugs themselves to the prices that physicians pay." Exhibit 59 (AWP010-0029 through AWP010-0032) is a true and accurate copy of that letter. It was created at or near the time by, or from information transmitted by, a person with knowledge of its contents, and was made and kept in the course of regularly conducted business activity.

60. On June 13, 2000, Nancy-Ann Min DeParle, Administrator, U.S. Department of Health and Human Services, made the following comment to the House Committee on Ways and Means: "[T]he President has for the last four or 5 years now proposed a law to help us to be able

to do this better, to make sure that we get the prices that physicians actually are paying." She was asked by Rep. Lloyd Doggett (D-Tex): "What you are saying is that there have been I believe four occasions when the administration has come to the Republican Congress and said please give us the tools to ensure that the taxpayer is not being ripped off and that they are paying the actual wholesale price and not some contrived wholesale price." In response, Ms. Min DeParle stated: "Unfortunately, yes, that is the case." *Legislation to Cover Prescription Drugs Under Medicare: Hearing Before the Committee on Ways and Means*, 106th Cong. 103 (2000) (statements of Nancy-Ann Min DeParle, Administrator, U.S. Department of Health and Human Services and Rep. Doggett). Exhibit 60 is a true and accurate copy of these statements. It was created at or near the time by, or from information transmitted by, a person with knowledge of its contents, and was made and kept in the course of regularly conducted business activity.

61. Shortly after Secretary Donna Shalala's May 2000 announcement of a plan to equate AWP with prices actually paid by physicians, 89 Members of Congress wrote her and stated: "These data do not take into account the fact that oncologists are chronically underpaid for their drug administration services in treating cancer patients—a fact that is widely recognized, including in your letter announcing the plan to reduce reimbursement. If reimbursement for drugs is drastically reduced, many physicians will be unable to continue providing cancer care in their offices, and patients will be deprived of a humane, convenient, and cost-effective treatment option. It is important to recall that reimbursement for cancer drugs is an issue that has been repeatedly addressed by Congress over the past few years . . . . It is disturbing that [HHS] would now seek to circumvent those congressional actions by redefining AWP." Letter from 89 Members of Congress to Donna Shalala, Secretary, HHS (July 28, 2000). Exhibit 61 is a true and accurate copy of a that letter. It was made at or near the time by, or from information transmitted by, a person with knowledge of the contents of the letter, and was made and kept in the course of regularly conducted business activity.

62. On September 5, 2000, Senator John Ashcroft stated in the U.S. Senate: "While there are indications that drug reimbursements have often exceeded doctors' and hospitals' costs, these margins have been used to help cover costs for professional services, which are inadequately reimbursed according to the cancer community, the General Accounting Office, and HCFA itself." 146 Cong. Rec. S8022, S8022 (daily ed. Sept. 5, 2000) (statement of Sen. Ashcroft). Exhibit 62 is a true and accurate copy of that statement. It was created at or near the time by, or from information transmitted by, a person with knowledge of its contents, and was made and kept in the course of regularly conducted business activity.

63. On September 25, 2000, Representative McHugh submitted into the Congressional Record a July 2, 2000 article by journalist Alan Emory. This article stated, in part: "Letters to Congress have stressed that oncologists deserve an increase above that price, not a reduction, and they point out that many hospitals and doctors cannot obtain the needed drugs at those prices. This is not the story of greedy drug manufacturers boosting prices to the point where some Americans travel to Canada to obtain medication at reasonable prices. It is not the story of doctors and hospitals pocketing huge markups. It is one about a reduction in compensation for doctors that may be cut even more to a point where the welfare of senior citizen cancer patients is endangered." 146 Cong. Rec. E1587, E1587 (daily ed. Sept. 25, 2000)

(*Watertown Daily Times* news article by Rep. McHugh). Exhibit 63 is a true and accurate copy of that statement. It was created at or near the time by, or from information transmitted by, a person with knowledge of its contents, and was made and kept in the course of regularly conducted business activity.

64. On September 25, 2000, Rep. Pete Stark stated in the Congressional Record: "Medicare has delayed reducing the level of reimbursement for various chemotherapy drugs, because of lobbying by some oncologists and drug companies that the profits are essential to cover the cost of running an oncology medical practice." 146 Cong. Rec. E1578, E1578 (daily ed. Sept. 25, 2000) (statement of Rep. Stark). Exhibit 64 is a true and accurate copy of that statement. It was created at or near the time by, or from information transmitted by, a person with knowledge of its contents, and was made and kept in the course of regularly conducted business activity.

65. In December 2000, Congress enacted the Medicare, Medicaid and SCHIP Benefits Improvement and Protection Act of 2000 ("BIPA"), which barred the Secretary from "directly or indirectly decreas[ing] the rates of reimbursement" for drugs covered by Part B until the Comptroller General had studied the issue of Medicare drug reimbursement. Pub. L. No. 106-554 § 429, 114 Stat. 2763 (2000). Exhibit 65 is a true and accurate copy of this part of the statute. It was created at or near the time by, or from information transmitted by, a person with knowledge of its contents, and was made and kept in the course of regularly conducted business activity.

66. In order to implement BIPA, in May 2001 HCFA issued a Program Memorandum to Intermediaries and Carriers instructing them to continue using AWPs provided in industry publications, not to use "any alternative sources of data for average wholesale prices," and to disregard the September 2000 instruction to equate AWP with actual prices paid by providers. *See* HCFA Transmittal Mem. AB-01-66, *Implementation of Medicare Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) Requirements for Payment Allowance of Drugs and Biologicals Covered by Medicare* (May 3, 2001). Exhibit 66 is a true and accurate copy of that memorandum. It was created at or near the time by, or from information transmitted by, a person with knowledge of its contents, and was made and kept in the course of regularly conducted business activity.

67. After Congress passed BIPA, HCFA Acting Administrator Michael M. Hash wrote a letter dated November 15, 2000 to Representative Tom Bliley of the Commerce Committee of the U.S. House of Representatives. In that letter, Mr. Hash commented that BIPA's freeze on the use of new AWP information from the United States Department of Justice "is a continuation of congressional efforts over the past several years to block Administration initiatives to lower drug prices." Exhibit 67 (HHC001-0357 through HHC001-0358) is a true and accurate copy of that letter. It was made at or near the time by, or from information transmitted by, a person with knowledge of its contents, and was made and kept in the course of regularly conducted business activity.

68. On November 26, 2001, Minnesota Medicaid official Cody Wiberg sent an email to various parties in response to a proposal by the President of the National Community Pharmacists Association to develop a "'perfect' pharmacy reimbursement formula." Mr. Wiberg stated: "What is needed is a better method of determining actual acquisition cost (AAC). In addition to AAC, a fee should be added that takes into account the average cost of dispensing a prescription and a reasonable profit. Such a fee might have to be double what we typically pay as a dispensing fee right now." Exhibit 68 (NYSHD-FOIL 00769 through 00772) is a true and accurate copy of this email. It was made at or near the time by, or from information transmitted by, a person with knowledge of its contents, and was made and kept in the course of regularly conducted business activity.

69. Exhibit 69 is a true and correct copy of a brief and a Statement Of Material Facts As To Which There Is No Genuine Issue, both of which were filed on or about July 10, 1991 by the Department of Health and Human Services in the U.S. District Court for the Western District of Missouri in *Missouri Pharmaceutical Association, et al. v. Stangler, et al.*, Case No. 91-4110. Ex. 69 was made at or near the time by, or from information transmitted by, a person with knowledge of its contents, and was made and kept in the course of regularly conducted business activity.

Additional Requests For Admission

70. Between 1991 and 1997, HCFA interpreted the term "average wholesale price" or "AWP" to mean drug prices published in national compendia such as the Red Book or Blue Book.

71. Ven-A-Care did not have "direct and independent knowledge" of the information upon which the allegations relating to Abbott in the 1995 complaint are based.

72. Before the effective date of the Balanced Budget Act of 1997, no federal statute or regulation required Medicare Part B to provide payment to Providers based on or in any way using AWP.

73. After the effective date of the Balanced Budget Act of 1997, no federal statute or regulation required Medicare Part B to provide payment to Providers based on or in any way using AWP.

74. After the effective date of the Balanced Budget Act of 1997, one or more federal statutes or regulations did require Medicare Part B to provide payment to Providers based on or using AWP.

75. During the entire Relevant Claim Period, no federal statute or regulation required Medicaid to provide payment to Providers based on or in any way using AWP.

76. During the entire Relevant Claim Period, no federal statute or regulation prohibited Medicare Part B from providing payment to Providers at the amount that Providers paid to acquire drugs.

77. During the entire Relevant Claim Period, the U.S. Government had authority to seek information from Providers about their acquisition costs for the Subject Drugs.

78. During the entire Relevant Claim Period, CMS had the authority to require Providers to indicate their actual acquisition cost for drugs on the claim forms submitted for payment by Medicare Part B.

79. During the entire Relevant Claim Period, Providers could have provided their actual acquisition cost for drugs on the claim forms submitted for payment under Medicare Part B.

80. During the entire Relevant Claim Period, CMS had the authority to require Providers to indicate their actual acquisition cost for drugs on the claim forms submitted for payment by Medicaid.

81. During the entire Relevant Claim Period, Providers could have provided their actual acquisition cost for drugs on the claim forms submitted for payment under Medicaid.

82. From November 25, 1991 to the effective date of BBA 1997, Medicare Part B could have paid for drugs at an EAC that was not based upon or in any way related to AWP.

83. During the entire Relevant Claim Period, State Medicaid Programs could have paid for drugs at an EAC that was not based upon or in any way related to AWP.

84. From November 25, 1991 to the effective date of BBA 1997, Medicare Part B could have paid for drugs at an EAC determined by surveys or studies of Provider acquisition costs.

85. During the entire Relevant Claim Period, State Medicaid Programs could have paid for drugs at an EAC determined by surveys or studies of Provider acquisition costs.

86. During the Relevant Claim Period, State Medicaid Programs were encouraged by HCFA/CMS to base payment for drugs at an EAC determined by surveys or studies of Provider acquisition costs.

87. During the entire Relevant Claim Period, no federal statute or regulation prevented Providers from seeking payment from Medicare Part B at the price they paid to acquire drugs.

88. During the entire Relevant Claim Period, no federal statute or regulation prevented Providers from seeking payment from Medicaid at the price they paid to acquire drugs.

89. It is the Plaintiff's position that a Provider who submitted a claim for payment to Medicare Part B or Medicaid for a drug knowing it would be paid at an amount that exceeded its acquisition cost submitted a false claim under the False Claim Act.

90. It is the Plaintiff's position that a Provider who submitted a claim for payment to Medicare Part B or Medicaid for a drug knowing it would be paid at an amount that exceeded its acquisition cost did not submit a false claim under the False Claim Act.

91. It is the Plaintiff's position that a Provider who submitted a claim for payment to Medicare Part B or Medicaid for a drug when it knew its acquisition cost for the drug was "far lower" (*see* Complaint, ¶ 3) than the AWP then published for the drug submitted a false claim under the False Claim Act.

92. It is the Plaintiff's position that a Provider who submitted a claim for payment to Medicare Part B or Medicaid for a drug when it knew its acquisition cost for the drug was "far lower" (*see* Complaint, ¶ 3) than the AWP then published for the drug did not submit a false claim under the False Claim Act.

93. It is the Plaintiff's position that a Provider who submitted a claim for payment to Medicare Part B or Medicaid for a drug when it knew its acquisition cost for the drug was "far lower" (*see* Complaint, ¶ 3) than the AWP then published for the drug, and did not return the difference to the Medicare or Medicaid program, submitted a false claim under the False Claim Act.

94. For at least some of the false claims Plaintiff alleges Abbott caused to be filed, it is Plaintiff's position that the Provider who filed the claim submitted a false claim under the False Claims Act.

95. For all of the false claims Plaintiff alleges Abbott caused to be filed, it is Plaintiff's position that the Provider who filed the claim submitted a false claim under the False Claims Act.

96. During the Relevant Claim Period, no federal statute or regulation provided that Abbott or other Manufacturers must report prices for drugs.

97. During the Relevant Claim Period, no federal statute or regulation defined the prices that Abbott or other Manufacturers must report to Publishers.

98. During the Relevant Claim Period, no federal statute or regulation defined the prices that Abbott or other Manufacturers reported to Publishers.

99. During the Relevant Claim Period, no federal statute or regulation regulated the prices that Abbott or other Manufacturers reported to Publishers.

100. During the Relevant Claim Period, no federal statute or regulation required Abbott or other Manufacturers to disclose their average sales prices to Publishers.

101. During the entire Relevant Claim Period, HCFA/CMS was aware that the term "Average Wholesale Price" or "AWP" referred to figures reported by Publishers.

102. During the entire Relevant Claim Period, HCFA/CMS was aware that AWP generally did not reflect discounts, rebates, and chargebacks associated with the sale of drugs by Manufacturers to wholesalers, distributors, and at least some Providers. (Throughout these requests, the word "generally" should be construed as it is used in paragraphs 35 and 50 of the Complaint.)

103. During the Relevant Claim Period, AWP was not an adequate estimate of the acquisition price paid for drugs by the Customers (*see* Complaint, ¶ 3) who submitted the claims Plaintiff alleges were false.

104. During the Relevant Claim Period, AWP represented a list figure and did not reflect several types of discounts.

105. During the Relevant Claim Period, no federal statute or regulation required Abbott or other Manufacturers to report prices to Publishers that incorporated all discounts available to certain wholesalers, distributors, or purchasers of drugs.

106. During the Relevant Claim Period, no federal statute or regulation required Abbott or other Manufacturers to report prices to Publishers that incorporated all rebates available to certain wholesalers, distributors, or purchasers of drugs.

107. During the Relevant Claim Period, no federal statute or regulation required Abbott or other Manufacturers to report prices to Publishers that incorporated all chargebacks available to certain wholesalers, distributors, or purchasers of drugs.

108. During the Relevant Claim Period, no federal statute or regulation required Abbott or other Manufacturers to report prices to Publishers that incorporated all discounts, rebates, and/or chargebacks available to certain wholesalers, distributors, or purchasers of drugs.

109. During the Relevant Claim Period, no federal statute or regulation prohibited Abbott or other Manufacturers from offering discounts, rebates, and or chargebacks to wholesalers, distributors, or purchases of drugs.

110. During the Relevant Claim Period, Medicare Part B reimbursed for one or more units of a Subject Drug based on or in reference to the Provider's cost to acquire that drug.

111. During the Relevant Claim Period, at least one State Medicaid Program reimbursed for one or more units of a Subject Drug based on or in reference to the Provider's cost to acquire that drug.

112. During the Relevant Claim Period, Medicare Part B reimbursed for one or more units of a Subject Drug based on or in reference to the Provider's Usual and Customary Charges.

113. During the Relevant Claim Period, Medicaid reimbursed one or more units of a Subject Drug based on or in reference to the Provider's Usual and Customary Charges.

114. During the Relevant Claim Period, the U.S. Government purchased one or more units of each of the Subject Drugs based on an amount arrived at through negotiations with Abbott.

115. Throughout the Relevant Claim Period, the U.S. Government purchased Vancomycin from Abbott at a price at least ten times less than the AWP then published by First DataBank.

116. By at least the end of 1994, the U.S. Government had purchased Vancomycin from Abbott at a price at least ten times less than the AWP then published by First DataBank.

117. Throughout the Relevant Claim Period, the U.S. Government purchased sodium chloride from Abbott at a price at least ten times less than the AWP then published by First DataBank.

118. By at least the end of the 1994, the U.S. Government had purchased sodium chloride from Abbott at a price at least ten times less than the AWP then published by First DataBank.

119. Throughout the Relevant Claim Period, the U.S. Government purchased dextrose in water from Abbott at a price at least ten times less than the AWP then published by First DataBank.

120. By at least the end of the 1994, the U.S. Government had purchased dextrose in water from Abbott at a price at least ten times less than the AWP then published by First DataBank.

121. Throughout the Relevant Claim Period, the U.S. Government purchased sterile water from Abbott at a price at least ten times less than the AWP then published by First DataBank.

122. By at least the end of 1994, the U.S. Government had purchased sterile water from Abbott at a price at least ten times less than the AWP then published by First DataBank.

123. During the Relevant Claim Period, Plaintiff is unaware of any evidence that Abbott submitted an AWP to any Publisher for any of the Subject Drugs.

124. During the Relevant Claim Period, Ven-A-Care is unaware of any evidence that Abbott submitted an AWP to any Publisher for any of the Subject Drugs.

125. During the Relevant Claim Period, neither HCFA nor CMS relied on any statement made directly to it by Abbott in setting payment rates or methodologies under Medicare Part B for any of the Subject Drugs.

126. During the Relevant Claim Period, no Medicare Carrier relied on any statement made directly to that Medicare Carrier by Abbott in providing payment or setting payment rates or methodologies under Medicare Part B for any of the Subject Drugs.

127. During the entire Relevant Claim Period, in connection with the Medicaid Drug Rebate Program, HCFA/CMS received data from Abbott that set forth AMPs for all of the Subject Drugs.

128. During some part of Relevant Claim Period, in connection with the Medicaid Drug Rebate Program, HCFA/CMS received data from Abbott that set forth AMPs for all of the Subject Drugs.

129. Plaintiff does not contend that AMP information provided to HCFA/CMS by Abbott for any of the Subject Drugs during the Relevant Claim Period was inaccurate because it was too high.

130. Plaintiff contends in this litigation that the published AWP for a Subject Drug should have reflected the average of all prices paid by all wholesalers for that drug.

131. Plaintiff does not contend in this litigation that the published AWP for a Subject Drug should have reflected the average of all prices paid by all wholesalers for that drug.

132. Plaintiff contends in this litigation that the published AWP for a Subject Drug should have reflected the average of all prices charged by all wholesalers for that drug.

133. Plaintiff does not contend in this litigation that the published AWP for a Subject Drug should have reflected the average of all prices charged by all wholesalers for that drug.

134. Plaintiff contends in this litigation that the published AWP for a Subject Drugs should have reflected the average of all prices paid by all Providers for that drug.

135. Plaintiff does not contend in this litigation that the published AWP for a Subject Drug should have reflected the average of all prices paid by all Providers for that drug.

136. Plaintiff contends in this litigation that the published AWP for a Subject Drug should have reflected the average of all prices paid to Abbott for that drug.

137. Plaintiff does not contend in this litigation that the published AWP for a Subject Drug should have reflected the average of all prices paid to Abbott for that drug.

138. Plaintiff is seeking damages in this litigation for reimbursement of Subject Drugs when the claim form submitted to Medicare by Providers contained a HCPCS Code or J Code but did not contain an NDC.

139. Plaintiff is not seeking damages in this litigation for reimbursement of Subject Drugs when the claim form submitted to Medicare by Providers contained a HCPCS Code or J Code but did not contain an NDC.

140. Plaintiff is seeking damages in this litigation for reimbursement of Subject Drugs when the claim form submitted to Medicaid by Providers contained a HCPCS Code or J Code but did not contain an NDC.

141. Plaintiff is not seeking damages in this litigation for reimbursement of Subject Drugs when the claim form submitted to Medicaid by Providers contained a HCPCS Code or J Code but did not contain an NDC.

142. During the Relevant Claim Period, for purchases of drugs made pursuant to Section 340 of the federal Public Health Act, 340B Providers were required to submit their actual acquisition cost of a drug to Medicaid when seeking reimbursement of such drug.

143. During the Relevant Claim Period, for purchases of drugs made pursuant to Section 340 of the federal Public Health Act, 340B Providers submitted their actual acquisition cost of a drug to Medicaid when seeking reimbursement of such drug.

144. As of August 15, 1975, the Secretary of HHS was aware that AWP data often was not closely related to the drug prices actually charged to and paid by Providers.

145. As of December 1977, HHS was not convinced that states continuing to reimburse at AWP had made a real effort to approach Provider's actual acquisition costs for drugs reimbursed by Medicaid.

146. In June 1984, HHS-OIG advised state Medicaid agencies that AWP cannot be the best—or even an adequate—estimate of the price providers generally pay for drugs, and that it represents a list price and does not reflect several types of discounts.

147. Prior to 1984, the Secretary of HHS lacked cumulative, well-documented evidence affirmatively demonstrating that AWP was in fact not an accurate measure of the prices generally paid by providers.

148. After 1984, the Secretary of HHS was aware of a widening base of documented evidence demonstrating that AWP significantly overstated the Provider's acquisition costs.

149. In or about 1984, HHS became convinced as a factual matter that there was a significant discrepancy between AWP and the actual purchase prices for drugs.

150. In June 1984, HHS-OIG recommended that HCFA revise the upper limit regulations applicable to Medicaid drug reimbursement to include a specific prohibition on use of AWP in establishing the EAC for those drugs.

151. In September 1984, HCFA believed that within the pharmaceutical industry, AWP meant undiscounted list price and that pharmacies purchased drugs at prices discounted significantly below AWP or list price

152. In September 1984, HCFA believed that excessive payments were being made nationwide for the ingredient cost of prescription drugs under the Medicaid program.

153. In September 1984, HCFA sent the June 1984 HHS-OIG Audit Report to all state Medicaid agencies in order to make them aware of the potential savings that could result if states would make a greater effort to determine more closely the price pharmacists pay for drugs, rather than using AWP.

154. As of September 17, 1985, HCFA believed that states could no longer claim to be applying their best estimates to determining prescription drug costs if they relied solely on AWP, unless they provided other evidence that supported a contrary conclusion.

155. On September 4, 1985, officials from HCFA's central office believed that states should be free to develop and adopt any method of drug pricing that resulted in a more accurate reflection of providers' costs since no specific methodology developed at the federal level was mandated.

156. As of 1987, HHS believed that published AWPs were not representative of the prices pharmacists actually paid for drugs because surveys showed that pharmacies generally purchased drugs at prices that were discounted significantly below AWP.

157. On May 16, 1988, HCFA believed there was a preponderance of evidence that AWP significantly overstated the price pharmacy providers paid for drug products and that AWP was not the price generally and currently paid by providers.

158. As of May 16, 1988, the HCFA Administrator was aware that AWP significantly overstated the price pharmacy providers actually paid for drug products.

159. As of May 16, 1988, the continued use of AWP as the basis for reimbursing providers under Medicaid resulted in significant overpayments to pharmacy providers.

160. In 1989, the HCFA Administrator believed that average wholesale price was significantly higher than actual costs and was somewhat comparable to the manufacturer's sticker price on a new car.

161. From 1989 to 1991, HCFA invalidated or threatened to invalidate state Medicaid programs in Louisiana, Arkansas, and Oklahoma that used undiscounted AWP as the benchmark for reimbursement and also refused to pay the federal share to such states. *See Louisiana v. U.S. Dep't of Health & Human Servs.*, 905 F.2d 877 (5th Cir. 1990); *In re Arkansas Dep't of Human Servs.*, 1991 WL 634857 (HHS Dept. App. Bd. Aug. 22, 1991); *In re Oklahoma Dep't of Human Servs.*, 1991 WL 634860 (HHS Dept. App. Bd. Aug. 13, 1991); *Rite Aid of Pa., Inc. v. Houstoun*, 171 F.3d 842, 847 (3d Cir. 1999).

162. As of October 5, 1989, HCFA believed that published AWP was not an acceptable measure of estimated acquisition cost because it was frequently inflated and did not reflect the various incentives, sales promotions, discounts and allowances that were routine terms of purchasing in the drug marketplace.

163. As of 1990, the Secretary of HHS believed that AWP rarely, if ever, reflected the prices actually paid by pharmacies.

164. As of 1990, the Secretary of HHS believed that the agency's policy since 1976 had been that AWP was not an acceptable measure of estimated acquisition cost.

165. From 1976 to 1990, the policy of HHS was that published AWPs were not an acceptable measure of estimated acquisition cost.

166. As of January 12, 1990, the position of the Secretary of HHS was that AWP significantly overstated the prices pharmacists were generally paying for prescription drugs.

167. As of October 20, 1992, HCFA was aware that the EAC of Vancocin/Vancomycin 500 ML was $5.00 while the median AWP for the same drug was $19.17, based on surveys of actual invoice prices at dialysis facilities during May 1991.

168. As of March 18, 1993, HCFA and state Medicaid officials agreed that pharmacies often used excess Medicaid reimbursements to cover their dispensing costs.

169. As of March 18, 1993, HCFA believed that pharmacies often used excess Medicaid reimbursements to cover their dispensing costs.

170. As of 1997, the Secretary of HHS believed that AWP was not the average price actually charged by wholesalers to their customers but rather a sticker price set by drug manufacturers and published in several commercial catalogs.

171. As of October 1, 1997, the HCFA Administrator believed that the published AWPs used by Medicare carriers to determine reimbursement did not resemble the actual wholesale prices available to the physician and supplier communities that billed for such drugs.

172. As of June 13, 2000, the HCFA Administrator believed that on several occasions the administration had unsuccessfully sought from Congress the tools necessary to ensure that HCFA was paying the actual wholesale price rather than a contrived wholesale price.

173. As of November 15, 2000, the HCFA Administrator believed that the Medicare, Medicaid and SCHIP Benefits Improvement and Protection Act of 2000 ("BIPA") was a continuation of congressional efforts to block initiatives to lower drug prices.

174. The reports and regulations listed on Schedules A and B of Defendant Abbott Laboratories' First Set of Requests for Production of Documents and Tangible Things to Plaintiff United States of America are public records or reports that set forth activity of various agencies of the U.S. Government.

175. On or about the time they were prepared, the U.S. Government distributed copies of those final reports listed on Schedule A of Defendant Abbott Laboratories' First Set of Requests for Production of Documents and Tangible Things to Plaintiff United States of America to State Medicaid directors. If the U.S. Government cannot make this admission for all of the listed reports, please list those reports listed on that Schedule A where the U.S. Government can make the admission.

Dated: November 30, 2007

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on November 30, 2007, a true and correct copy of the foregoing **ABBOTT LABORATORIES, INC.'S REVISED FIRST SET OF REQUESTS FOR ADMISSION TO PLAINTIFF UNITED STATES OF AMERICA AND RELATOR VEN-A-CARE OF THE FLORIDA KEYS, INC.** was served upon:

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/s/ R. Christopher Cook_____
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